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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,632	11/25/1997	ELAZAR RABBANI	ENZ-53(C)	4638
28171 7590 01/08/2008 ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR)			EXAMINER	
			WOLLENBERGER, LOUIS V	
NEW YORK,	NY 10022	ART UNIT PAPER NU		PAPER NUMBER
			1635	
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•			01/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary		Application No.	Applicant(s)			
		08/978,632	RABBANI ET AL.			
		Examiner	Art Unit			
		Louis V. Wollenberger	1635			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 15 Oc	<u>ctober 2007</u> .				
,	This action is FINAL . 2b)⊠ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
5)□ 6)⊠ 7)□	Claim(s) <u>246-252,255,257-260 and 264-270</u> is/4a) Of the above claim(s) is/are withdrav Claim(s) is/are allowed. Claim(s) <u>246-252,255,257-260 and 264-270</u> is/Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration. Vare rejected.				
Applicati	on Papers					
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Example 1.	epted or b) objected to by the liderawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachmen		,, ((DTO 442)			
2) Notic 3) Infor	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

DETAILED ACTION

Location of the Application

The location of the application has changed. The application has been docketed to Examiner Louis Wollenberger in Art Unit 1635.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/07 has been entered.

Status of Application/Amendment/Claims

Applicant's response filed 10/15/07 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 3/19/07 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 246-252, 255, 257-260 and 264-270 are pending and examined herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 246-252, 257-260, and 264-266 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 245-255, 257-262, 266-268, 272-280, 284-286, and 290-298 of copending Application No. 08/978,633.

Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting application 08/978,633 claims a nucleic acid construct and composition thereof comprising a polynucleotide tail, an antibody, and a chemical modification or a ligand.

Therefore, one of ordinary skill in the art would conclude that the invention defined in the claims at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the conflicting application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The list of potentially conflicting patent applications in the instant case is extensive, and includes 08/978,634; 08/978,637; and 08/978,635, against which a provisional double patenting rejection may be made, as each of the applications contains claims to constructs and compositions similar if not identical to those now claimed in the instant application.

It is Applicants' burden to file appropriate terminal disclaimers for all relevant applications listed above. Furthermore, if Applicants are aware of any pending applications or patents, which are not listed above, it is Applicants' duty to disclose these applications or patents, and to submit an appropriate terminal disclaimer over these applications or patents as pertinent to the instant invention.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 268-270 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record set forth in the office action mailed on 9/23/2005. This is a new matter rejection.

Claim 268 recites a nucleic acid construct comprising a ligand "in two or more locations on said construct." As noted by the previous Examiner, there does not appear to be specific

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support for a recitation of "two or more locations" within the context of the claimed invention. Therefore, the claimed invention lacks written description support. Dependent Claims 269 and 270 are rejected therefor.

Applicant's arguments presented 10/15/2007 have been considered but are not persuasive. Applicant points to the drawings for written description support.

However, schematic illustrations of circular constructs bearing 2, 4, 6, 8, and 11 nonnucleic acid ligands do not by themselves clearly convey to one of skill the word-for-word limitation "two or more." The drawings together with the specification adequately describe constructs comprising one or more non-nucleic ligands. Converting pictoral content into descriptive text is inherently subjective, and amounts to the introduction of a brief description of the drawings after the filing date. In the absence of accompanying text in the original application, one can only presume or at best speculate what information an applicant may or may not have specifically intended to communicate to the reader by a schematic illustration. The absence of such limiting text does not entitle applicant to later claim specific embodiments broadly embraced by the illustrations. While it is clear that the drawings do embrace embodiments of "two or more" it is not clear from the original application that this was an embodiment. Indeed, according to applicant's rationale, the drawings show "three or more," "four or more" and "eight or more." These limitations are, however, not clearly supported by the specification as filed.

Accordingly, the claims are rejected for lack of written description support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 246-252, 255, 257-260 and 264-266 are rejected under 35 U.S.C. 102(e) as being anticipated by Craig et al. (US Patent 5,766,902).

Craig et al. taught methods for enhancing the targeted delivery of nucleic acid molecules to cells by coupling the nucleic acid to a ligand having affinity for a cell surface molecule or receptor. The ligand facilitates uptake of the nucleic acid by receptor mediated endocytosis (cols. 2-6). The nucleic acid molecule preferably comprises at least one transcription unit encoding a protein or RNA molecule such as an antisense oligonucleotide or ribozyme (col. 3, lines 59-62; col. 4, lines 24-28). The nucleic acid molecule may be plasmid DNA or a recombinant viral

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genome, such as any adenoviral or retroviral vector (col. 12, lines 1-25). Thus, the types of nucleic acids contemplated for use with the invention include single and double stranded, linear and circular, DNA and RNA molecules. The ligand may be any molecule, small or large, capable of binding to a cell and/or facilitating delivery into the cell (col. 4, lines 29-45), including proteins, carbohydrates, and metal ions. Specifically recommended are antibodies, growth factors, and fusogenic peptides (col. 4 and 8). The ligand may be chemically conjugated by covalent bonded to the nucleic acid (col. 8, lines 14-15). Covalent conjugation would necessarily result in modification of the sugar, phosphate, or nucleobase portion of one or more nucleotides of the nucleic acid. Therefore, the construct would comprise a modified nucleotide.

With regard to claim 255, the construct as claimed in claim 246 does not require a "nucleotide analog." Therefore, claim 255 further defines an optional element and does not distinguish the claimed invention from that described by Craig et al.

Similar reasoning applies to the invention defined in claims 259 and 260. Craig et al. describe at the very least natural polymeric, non-nucleic acid entities such as proteins that may be coupled to nucleic acid constructs encoding proteins and/or RNAs. Claims 259 and 260 do nothing more than further define synthetic polymers, which are optional elements of the invention claimed in claim 257.

With regard to claim 266, although Craig et al. is silent with respect to charge properties of the ligand/nucleic acid complexes, Craig et al. anticipates all of the claimed structural limitations. Moreover, proteins may, depending on the pH, carry a net negative or positive charge, which charge would supplement or offset the charge of the nucleic acid. Therefore, there is reason to believe the complexes of Craig et al. may, in some instances, be neutral.

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Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Burden is shifted to Applicant to show the products disclosed by Craig et al. do not include neutral complexes.

Accordingly, Craig et al. anticipates the invention as now claimed.

Claims 246-252, 255, and 264-270 are rejected under 35 U.S.C. 102(b) as being anticipated by Low et al. (US Patent 5,108,921).

The claims read on biotinylated and folate-modified polynucleotides. Biotin modified nucleotides are considered to represent both "modified nucleotides" and "nucleotide analogs' absent convincing evidence to the contrary. An explicit definition clearly excluding such an interpretation is not found in the instant specification. Moreover, Low et al. claim nucleic acid analogs as part of their invention (claims 14 and 15).

Low et al. taught a method for enhancing the internalization of polynucleotides into cells in vitro and in vivo, comprising the incorporation of biotin and/or folate into the polynucleotide

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(cols. 1-9; Examples 12, 16, 17, 21-23, beginning at col. 12; and claims 1-27). Biotin and folate are said to promote endocytosis of the biotinylated or folate-modified polynucleotide (cols. 2-3, for example). The method can be applied to enhance the uptake of virtually any desired polynucleotide, including plasmid DNA and viral vectors, artificial chromosomes, antisense oligonucleotides, ribozymes and many other nucleic acid molecules, including retroviral genomes and transcription units (col. 3, lines 25-50; Example 12 and 16; claim 17; and see list of possible polynucleotides at col. 5). Particular examples show expression biotinylated plasmids encoding an ampicillin or kanamycin resistance gene—i.e., mRNAs. By nature, biotinylation and folate modification, according to the method taught and exemplified, would result in multiple biotins and/or folates at multiple locations in the nucleic acid molecule. Moreover, Low et al. expressly contemplate incorporating multiple molecules of biotin and foliate at multiple locations in the molecule to take advantage of each type of receptor (col. 8, lines 15-40). Biotin and folate may be covalently or non-covalently linked to the polynucleotide (cols. 5, beginning at line 58 to col. 8, line 40; and see examples cited above). End-labeling methods are also included (col. 6, bottom).

Accordingly, Low et al. anticipates each and every aspect of the instant claims.

Claims 246-249, 252, 255, 267, and 268 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al. (1990) *Proc. Natl. Acad. Sci.* 87:1451-1455.

The claims read on phosphorothioated plasmid DNA such as that taught by Olsen et al.

Olsen et al. taught a method for site directed mutagenesis of genes contained in plasmid DNA, comprising selective incorporation of one or more deoxynucleoside 5'-[\alpha-

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thio]triphosphates (see Introduction, Results, and Conclusion, pp. 1451-1455). Incorporation of phosphorothioates produces sites of nuclease resistance in the plasmid, which may be used to advantage to incorporate mismatched bases (Results, page 1452). Accordingly, Olsen et al. taught a method for producing phosphorothioate-modified plasmid DNA encoding mutant genes, i.e., mRNAs. The DNA contains both modified and unmodified nucleotides, is modified along the sugar phosphate backbone, which confers nuclease resistance.

Thus, Olsen et al. anticipates the instant claims.

Claims 246-249, 252, 255, 257-260, and 264-268 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al. (1993) *Transplantation Proceedings* 25:138-139.

Hirsch et al. taught a method for targeted transfection of plasmid DNA, comprising covalently coupling the DNA to a monoclonal antibody. In one example, the plasmid DNA encodes the neomycin resistance gene Fig. 1 and results, pp 138-9). It is said the conjugated plasmid is effectively transfected into cells and can result in stable long term expression of the encoded gene. The monoclonal antibody provides cell targeting specificity, as in the case demonstrated wherein the cells transfected carried the CD3 surface antigen (Discussion, page 139). As such, it is clear Hirsch et al. teach using the method with other antibodies to selectively target a cell population based on distinctive cell surface attributes.

With regard to claim 266, although Hirsch et al. is silent with respect to charge properties of the ligand/nucleic acid complexes, Hirsch et al. anticipates all of the claimed structural limitations. Moreover, antibodies may, depending on the pH, carry a net negative or positive

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charge, which charge would supplement or offset the charge of the nucleic acid. Therefore, there is reason to believe the complexes of Hirsch et al. may, in some instances, be neutral.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Burden is shifted to Applicant to show the products disclosed by Hirsch et al. do not include neutral complexes.

With regard to claim 268, the coupling method in solution used by Hirsch et al. would provide conditions suitable to the coupling of more than one antibody. There is no reason to believe the method resulted in one and only one antibody being coupled to the plasmid.

Accordingly, Craig et al. anticipates the invention as now claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 250, 251, 269, and 270 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (1993) *Transplantation Proceedings* 25:138-139 as applied to claims 246-249, 252, 255, 257-260, and 264-268 above, and further in view of Keating et al. (US Patent 6,503,755) and Bos et al. (1992) *Hybridoma* 11:41-51.

The supreme court in KSR International Co. v. Teleflex Inc., 550 U.S.____, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness consistent with the approach laid down by Graham. Exemplary rationales include (A) Combining prior art elements according to known methods to yield predictable results; (C)

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Use of a known technique to improve similar devices in the same way; and (D) Applying a known technique to a known device ready for improvement to yield predictable results. All three rationales apply here, as follows.

The claims read on linearized plasmids.

Hirsch et al. is relied on for the reasons given above.

Hirsch et al. do not teach linearized plasmids.

However, the prior art taught that, under some conditions and depending on cell type, it may be preferable to linearize plasmid DNA prior to transfection of mammalian cells.

For example, Keating et al. taught improved methods for transfecting mammalian cells with plasmid DNA. It is taught that the plasmid DNA may be linearized prior to introduction into the cells, and that under some conditions linearized plasmid DNA can result in slightly higher transfection efficiencies relative to supercoiled DNA (col. 6, lines 27-36; Example 1, col. 10, lines 15-20; and see Examples 2 and 3).

Bos et al. echo Keating et al., teaching that the transfection efficiency of hybridoma cells with a plasmid, pSV2-neo, increased two-fold after linearization as compared to intact plasmid when using HEPES buffered Saline (see Abstract and Results).

Thus, it would have been obvious to one of skill at the time of invention to combine the antibody-mediated transfection method of Hirsch et al. with the linearization technique of Keating et al. or Bos et al. to further enhance the cell targeting and uptake of the plasmid DNA. The methods could have been combined with no significant or apparent change in their respective functions, wherein the antibody provides for cell targeting specificity and the linearization provides for enhanced uptake. Stated another way, it would have been obvious to

apply the techniques of Keating et al. or Bos et al. to the antibody-coupled plasmids of Hirsch et al. to produce a linearized, antibody-conjugated plasmid with predictable properties.

The methods complement one another. As a result, the combination would have combined the benefits taught individually by Hirsch et al., Keating et al., and Bos et al. It would be the normal desire of any scientist in the field to achieve optimal transfection efficiency in the target cell population by applying those techniques, singly or in combination, known in the prior art to enhance plasmid DNA transfection.

For these reasons, then, the instantly claimed invention is considered to be *prima facie* obvious.

Prior art made of record but not currently relied on

The following prior art is made of record and is not relied upon, but is considered pertinent to applicant's disclosure.

Ramsay-Shaw et al. (US Patent 5,683,869) taught boranophosphate modified oligonucleotides for incorporation into DNA Vectors. The boranophosphate linkages are said to confer nuclease resistance. The modified vectors can be used for a variety of purposes including directed gene transfer and expression (col. 16, lines 15-45).

Putney et al. (1981) *Proc. Natl. Acad. Sci.* 78:7350-7354 taught methods for making and using phosphorothioate modified plasmid DNA.

Myers et al. (EP 0 273 085) taught methods for making and using polynucleotide-EGF conjugates for targeted transfection and/or transformation of mammalian cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/ Examiner, AU 1635 December 26, 2007